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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,979	05/21/2004	Steven M. Ruben	PZ028P2C1	8748

22195 7590 04/28/2006

HUMAN GENOME SCIENCES INC  
INTELLECTUAL PROPERTY DEPT.  
14200 SHADY GROVE ROAD  
ROCKVILLE, MD 20850

EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 04/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/849,979

Applicant(s)

RUBEN ET AL

Examiner

Prema M. Mertz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 March 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 25-48 is/are pending in the application.
- 4a) Of the above claim(s) 48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>5/21/04, 4/20/05</u> . | 6) <input checked="" type="checkbox"/> Other: <u>IDS 2/3/06</u> .                       |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group I (claims 25-47) in the reply filed on 3/14/2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Furthermore, Applicants request rejoinder of the subject matter of Groups I and II (see In re Ochiai (37 USPQ2d 1127 (Fed. Cir. 1995)), in which a new, unobvious material is used in a known process. Ochiai determined that a process was free of the prior art if it employed a product, which was free of the prior art. However, only if the product claims of Group I are found allowable, the subject matter of Group I will be rejoined with the process claims of Group II, if the process claims are of the same scope as the allowable product claims.

Claims 25-47 encompassing an antibody to a protein of amino acid sequence set forth in SEQ ID NO:139 will be examined in the instant application.

### *Specification*

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. It is suggested that the title be amended to recite the claimed antibody.

### *Claim rejections-35 U.S.C. 101*

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 25-47 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The claims are directed to an antibody to a polypeptide 508 amino acids in length. The invention encompassed by this claim has no apparent or disclosed patentable utility. This rejection is consistent with the current utility guidelines, published on 1/5/01, 66 FR 1092. The instant application has provided a description of a protein, but does not disclose a specific and substantial biological role of this protein or its significance. There is no biological activity, phenotype, disease or condition, or any other specific feature that is disclosed as being associated with the polypeptide of amino acid sequence set forth in SEQ ID NO:139. The mere identification of the polypeptide is not sufficient to impart any particular utility to the claimed polypeptide without any information as to the specific properties of polypeptide. Since significant further research would be required of a person skilled in the art to determine how the claimed polypeptide is involved in any activities, the asserted utilities are not substantial.

Furthermore, since the asserted utility is not present in a ready-to-use, real-world application, the asserted utility is not substantial.

The specification asserts several utilities for the polypeptide of SEQ ID NO:139, that are not necessarily related to its biological activities; however, none of these asserted utilities meets the three-pronged test of being credible, specific and substantial. Each will be addressed in turn:

1. *for differential identification of tissue or cell type present in a biological sample.* This asserted utility is not specific or substantial. The employment of a protein of the instant invention as a tissue specific marker is not a substantial or specific utility since specific proteins for brain

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tissue were already known in the art. All human proteins can invariably be classified into two categories, those which are expressed in a tissue or developmentally specific manner and those, which are expressed ubiquitously. It can be alleged that any protein, which is expressed in a tissue specific manner can be employed to detect the tissue in which it is expressed in a sample. Alternately, a human protein, which is expressed ubiquitously can be employed to detect the presence of any human tissue in a sample. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker, which is neither a specific or substantial utility.

2. *to produce antibodies against the polypeptides.* This asserted utility is not specific or substantial. Since antibodies can be made to any polypeptide, the asserted utility is not specific to the polypeptide of amino acid sequence set forth in SEQ ID NO:139. Furthermore, the specification does not disclose how the antibodies can be used, and therefore further significant research would be required on one skilled in the art to determine how to use the claimed antibodies. Since the asserted utility is not presented in a ready-to-use, real-world application, the asserted utility is not substantial.

3. *for treating, preventing, detecting and/or diagnosing neural and neurodegenerative disorders.* This asserted utility is not specific or substantial.

The specification (page 85, [1097]) alleges that:

“The tissue distribution indicates that the polynucleotides and polypeptides corresponding to the gene encoding this protein would be useful for the detection, diagnosis, prevention and/or

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treatment of neurodegenerative disease states and behavioral disorders such as Alzheimer's Disease, Parkinson's Disease, Huntington's Disease, Tourette Syndrome, schizophrenia, mania, dementia, paranoia, obsessive compulsive disorder, panic disorder, learning disabilities, ALS, psychoses, autism, and altered behaviors, including disorders in feeding, sleep patterns, balance, and perception.”

The specification also alleges that:

“In addition, the gene or gene product may also play a role in the treatment and/or detection of developmental disorders associated with the developing embryo, or sexually-linked disorders. Elevated expression of this gene product within the frontal cortex of the brain indicates that it may be involved in neuronal survival; synapse formation; conductance; neural differentiation, etc. Such involvement may impact many processes, such as learning and cognition. Additionally, the amygdale processes sensory information and relays this to other areas of the brain including the endocrine and autonomic domains of the hypothalamus and the brain stem. Thus, polynucleotides and polypeptides corresponding to this gene may also be useful for the detection and/or treatment of neural disorders that impact processes mediated by the amygdala. Protein, as well as, antibodies directed against the protein may show utility as a tumor marker and/or immunotherapy targets for the above listed tissues.”

The specification (page 84, [0195]) asserts that since the gene encoding the protein is expressed primarily in whole brain tissue, as well as brain specific tissues such as hypothalamus, frontal cortex, cerebellum, amygdala, and hippocampus tissues, as well as other brain specific tissues, the protein would be useful for the detection, diagnosis, prevention and/or treatment of neurodegenerative disease states (page 85, [0197]). However, the specification does not disclose

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the role of the protein in any of these conditions or the result of administering the protein or antibodies to the protein in any of these conditions, *in vitro* or *in vivo*.

Furthermore, since many antibodies can and are used as therapeutic reagents, the asserted utility is not specific to the claimed antibody. Since the asserted utility is not presented in a ready-to-use, real-world application, the asserted utility is not substantial.

4. *to use the protein or antibodies as a tumor marker and/or immunotherapy targets for the above listed tissues.* This asserted utility is not specific or substantial. There is no experimental evidence presented in the specification for the utility of the protein or antibodies to the protein to be used as a tumor marker. The specification asserts that the gene is primarily expressed in brain tissue. The specification does not provide any evidence of differential expression of the gene in normal and tumor tissue. Therefore, since the asserted utility is not presented in a ready-to-use, real-world application, the asserted utility is not substantial.

***Claim rejections-35 USC § 112, first paragraph***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 25-47 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantially asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know

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how to use the claimed invention. The instant specification does not disclose a biological activity for the claimed antibody, therefore, there is no specific and substantial asserted utility or well established for the claimed antibody to the protein of amino acid sequence set forth in SEQ ID NO:139.

### ***Conclusion***

Claims 25-47 are rejected.

No claim is allowed.

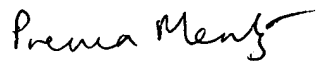
### ***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867.

Official papers filed by fax should be directed to (571) 273-8300. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Prema Mertz Ph.D., J.D.  
Primary Examiner  
Art Unit 1646  
April 20, 2006